



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

JUN 9 2000
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Marvin Rapaport, M.D.
436 North Bedford Drive, #306
Beverly Hills, California 90210

RE: Docket No. 78N-0301

Dear Dr. Rapaport:

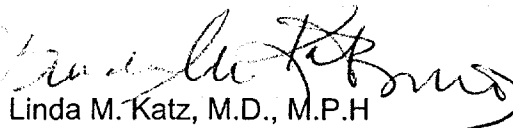
Reference is made to your letters dated April 1, 2000 and May 22, 2000, requesting a meeting between Mr. Seiichi Sato, you, and the Agency regarding your submissions for Satogesic plaster and future directions. Prior to determining whether a meeting will be necessary, you would need to provide us with a formal meeting request consisting of a complete briefing package containing the history of the development of Satogesic Medicated Pads, all correspondence with the Agency, a synopsis of all studies done, a comparison of your new formulation to the old formulation, and specific questions that you wish the Agency to address.

This meeting, if deemed necessary, will be a public feedback meeting open to any interested parties. Prior to the meeting, an announcement of the meeting will be placed in the agency's Dockets Management Branch. This is done because the rulemaking to establish a monograph for over-the-counter (OTC) external analgesic drug products is a public process.

There is no assurance that the Satogesic Medicated Pads product will eventually be covered by the final monograph. If you wish to meet with the Agency in private, you will need to submit a formal pre-investigational new drug (pre-IND) meeting request to the Division of Dermatologic and Dental Drug Products. That meeting will be targeted to evaluate your development plan towards a New Drug Application filing.

If you have any questions, please contact Elizabeth F. Yuan, R.Ph., Regulatory Project Manager, at 301-827-2222.

Sincerely yours,


Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

78N-0301

LET86 /Ans